



U.S. Military Immunization Program

Science - Quality - Care - Confidence

**Armed Forces Epidemiological Board
*22 March 2005***

COL John D. Grabenstein, RPh, PhD
Military Vaccine Agency
U.S. Army Medical Command

2003 *TIME* PERSON OF THE



Joe Raedle / Getty Images





U.S. Military Immunization Today

www.vaccines.mil

Endemic Disease Threats

(universal, occupational, +/- geographic)

- Hepatitis A
- Hepatitis B
- Influenza A&B
- Japanese encephalitis
- Measles, mumps, rubella
- Meningococcal A,C,Y,W-135
- Poliomyelitis
- Rabies
- Tetanus, diphtheria (Td)
- Typhoid fever
- Varicella (chickenpox)
- Yellow fever

Bioweapon Threats

- Anthrax
- Smallpox (vaccinia)

Desirable:

- Pertussis, adult (Tdap)
- Papillomavirus
- Adenovirus types 4, 7
- Botulism
- Meningococcal group B
- Plague
- Et cetera*



- **Anthrax (science, program, law/reg)**
- **Smallpox (science, program)**
- **Influenza (logistics, policy)**
- **Vignettes:**
 - **Meningococcal conjugate**
 - **Pertussis—adult (Tdap)**
 - **Papillomavirus**
 - **Japanese encephalitis**
 - **Other**
 - **Adenovirus - addressed separately**



anthrax vaccine immunization program

a matter of health. a matter of trust. a matter of national security.

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Your health and safety are our #1 concerns.

The anthrax vaccine is safe and effective.

The threat from anthrax is deadly and real.

Vaccination offers a layer of protection in addition to antibiotics and other measures needed for certain members of the Armed Forces.





Anthrax Vaccine Immunization Program (AVIP)

- **Scientific Issues**
 - **More safety data than ever**
 - **More long-term safety data than ever**



Science Underlying Anthrax Vaccine

Science:

- **Anthrax: Evidence for vaccine effectiveness**
- Brachman study, 1,249 people, *Am J Public Health* 1962
- Rhesus monkeys: 62 of 65 survive inhalational challenge
- Rabbits: 115 of 118 survive
- FDA actions: 1970, 1985, 2003, 2004
- National Academy of Sciences: 2002
- **Anthrax: Evidence for vaccine safety**
- 18 20 human safety studies, 34 peer-reviewed publications
- FDA actions: 1970, 1985, 2003, 2004
- National Academy of Sciences: 2002
- ACIP-2001, CDC-2005 (dose-reduction/route-change)



Anthrax Vaccine Safety Litany

- **Brachman Study, *Am J Public Health* 1962; 52:632-45 (n = 379)**
- **CDC Observational Study, *Fed Reg* 1985; 50:51002-117 (6,986)**
- **Ft Detrick Multi-Vaccine Studies, *BJHH* '58, *Ann Intern Med* 1965, 1974, 1981 (99)**
- **Fort Detrick Special Immunization Program, *Vaccine* 2001 (1,583)**
- **Fort Bragg Booster Study (after Persian Gulf War), *Vaccine* 2002 (495)**
- **USAMRIID Reduced-Dose / Route-Change Study, *Vaccine* 2002 (173)**
- **Canadian Forces Safety Survey, *Military Medicine* 2004 (576)**
- **TAMC-601 Survey, *MMWR* 2000; 49:341-5, *J Occup Environ Med* 2003 (601)**
- **US Forces Korea Records, *MMWR* 2000; 49:341-5, *Vaccine* 2003 (2,824)**
- **VAERS review by AVEC, *Pharmacoepidemiol & Drug Safety* 2002, 2004 (1,623)**
- **ROTC Cadets, Ft Lewis, *Med Surveil Mon Rep* 2001; 7(5):9-11 (73)**
- **USAF Air Combat Command Study, *Military Medicine* 2002 (4,045)**
- **Fort Stewart Pregnancy Study, *JAMA* 2002 (4,092)**
- **Aviator Flight Physical Examinations (3,356)**
- **USAF Visual Acuity Study (958)**



Male Fertility Study

- **Catherino WH**, et al. The anthrax vaccine does not affect semen parameters, embryo quality, or pregnancy outcome in couples with a vaccinated male military service member. *Fertility & Sterility* 2005;83:480-483.
- **Subjects:** 254 vaccinated men, 791 unvaccinated men; Oct 1999 to Dec 2003. Walter Reed Army Medical Center Assisted Reproduction Technologies Program. Data about vaccination obtained at oocyte and sperm retrieval.
- **Results:** Groups comparable for
 - semen concentration (million sperm per milliliter),
 - sperm motility (movement),
 - sperm morphology (shape),
 - need for intracytoplasmic sperm injection,
 - rate of fertilization of mature oocytes (eggs),
 - embryo transfer, and
 - clinical pregnancy.

Diagnosis of male-factor infertility less common in anthrax-vaccinated men than in unvaccinated men.



Disability Discharges

- **Sulsky SI**, et al. Disability among U.S. Army personnel vaccinated against anthrax. *Journal Occupational & Environmental Med* 2004;46:1065-1075.
- **Subjects:** U.S. Army personnel receiving ≥ 1 dose of anthrax vaccine adsorbed (AVA) between Mar 98 and Feb 02 vis-à-vis disability evaluation.
- **Methods:** 716,833 active-duty Soldiers (154,456 vaccinated) over 4.25 years. Cox proportional-hazard models for risk of disability evaluation.
- **Results:** Adjusted hazard ratio (HR) 0.96 (95% CI: 0.92, 0.99). Unadjusted rates: 140 per 100,000 person-months if unvaccinated, 68 per 100,000 person-months if anthrax-vaccinated.
- Separate adjusted HRs for men, women, permanent and temporary disability, musculoskeletal and neurological conditions similar, 0.90 to 1.04. Latency assumptions did not affect results.
- **Conclusion:** Anthrax vaccination does not increase risk of disability evaluation, nor granting of disability finding.



Long-term Safety Data: Lab Workers

- **Pittman PR**, et al. Long-term health effects of repeated exposure to multiple vaccines. *Vaccine* 2004;23:525-36.
- **Workers:** 155 former biolab workers, 1943 to 1969, median 154 vaxtns or skin tests, median 17.3 y elapse. 92% received anthrax vaccine. 1943 to 1996. Interval from 1st vaccination to survey was 15 to 55 y (mean 43.1 y). Mean age: 69 years old.
- **Controls:** 265 community controls from central Maryland matched on age, ethnicity and gender.
- **Results:** Lab workers reported fatigue more than controls, but fatigue not associated with # of injections, # of vaccines, or time. No differences for self-reported medical conditions. Several laboratory abnormalities were more common in workers, but none clinically significant. Frequency of monoclonal spikes or paraprotein peaks (12.5% vs 4.5%), but no association with lifestyle, vaccine exposure, or medical conditions.
- **Conclusion:** Intensive vaccination is not associated with an elevated risk of disease or medical condition.



Due Diligence

Isolated public assertions that DoD withholds evidence regarding (lack of) safety of its vaccination programs.

If AFEB desires any information not presented to it, please advise civilian leadership.



Anthrax Vaccine Immunization Program (AVIP)

- **Program Issues:**

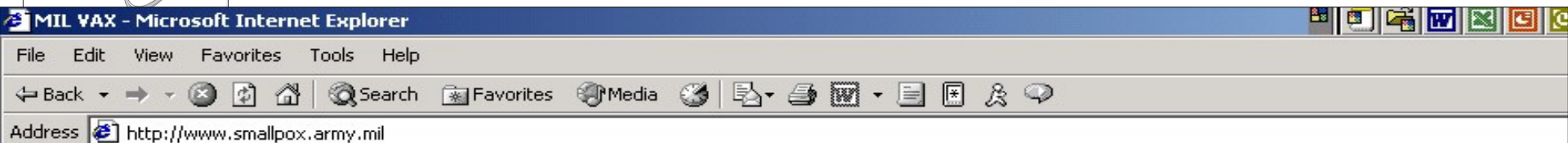
- Full stop, due to injunction 27 Oct 04
- Mar 98 to Oct 04: 5.2 million doses to 1.3 million people
- BioPort production steady, inventory accumulating

- **Legal / Regulatory Situation:**

- Judge deems AVA not indicated for inhalation anthrax
- remands Jan 04 final rule to FDA, lacked comment
- FDA opens 90-day comment period; ends 29 Mar 05
- DoD requests. FDA issues EUA, 6-dose pre-exp, 27 Jan 05
- USDC for DC hearing 21 Mar 05 to modify injunction
 - If modified, DoD would resume AVIP under EUA, pending FDA action on final order on AVA license status
- EUA for 3-dose post-exp vaccination also encumbered



Smallpox Website - www.smallpox.mil



THE DANGER

THE VACCINE

THE PRIORITY

THE STRATEGY

adverse event info

education toolkit

resource center

SMALLPOX VACCINATION PROGRAM

[contact us](#)

- Smallpox is contagious, deadly, and would disrupt military missions.
- Smallpox vaccine prevents smallpox and we will use it carefully.
- Preserving the health and safety of our people is our top concern.
- The Defense Department's smallpox vaccination program is part of our national strategy to safeguard Americans against smallpox attack.

MIL VAX

[DoD Begins Smallpox Vaccination Program](#)

[SVP Online Proficiency Training](#)

[DoD's Smallpox Vaccination Lessons Learned](#)

[MM](#)

Last Updated 01/24/2003

[http://
www.smallpox.mil](http://www.smallpox.mil)



DoD Smallpox Vaccination Program ***as of 15 Mar 05***

- **Response teams, hospital workers, operational forces**
 - **Screened: 830,000 - Vaccinated: 768,616**
 - **Primary: 71% - Male: 88%**
- **Exemption process working well**
 - **Eczema vaccinatum— 0 — Progressive vaccinia— 0**
- **Education working well, but we can do better**
 - **Autoinoculation—79**
 - **Contact transfer vaccinia—53: “Don’t let guard down at home.”**
 - **Family— 22, intimate— 18, friend— 13, patient— 0**
 - **Peri-vaccination Pregnancy—75% undetectable**
- **VIG treatments more rare than expected: Burn— 1, eye— 2**
- **Encephalitis— 1**
- **Myo-pericarditis—94: Suspect— 9, probable— 81, confirmed— 4**
- **Deaths: Possible— 1 (lupus-like illness) Unrelated— 6**
- **Derived from 1,611 VAERS reports and other sources**



MILVH Network Myo-pericarditis Registry

- **N=94 cases, 87 full review**
 - **Confirmed 5%**
 - **Probable 86%**
 - **Suspect 7%**
- **Age 25 ± 5 y (range 19-43)**
- **Male 98%**
- **Caucasian 84%**
- **Primary vaccinee 97%**
- **Onset of Sxs 10 ± 3.8 d (range 1 to 25)**
- **Cardiac enzyme \uparrow 86%**
- **ECG abnormal 86%**
- **Echo abnormal (20/68) 29%**
- **Cath abnormal (4/28) 14%**

- **Avg symptom duration 42.5 h**
Acute chest pain, not fatigue
- Followup with symptoms=Yes**
 - **6 to 12 weeks (n=44) 20%**
 - **6 to 12 months (n=38) 3%**
- **MRI (n=16) ? findings**
- **Indium-111 WBC ? findings**

Challenges:

➤Clinical:

- **Diagnostic suspicion, reporting**
- **Persistent discomfort, prognosis**

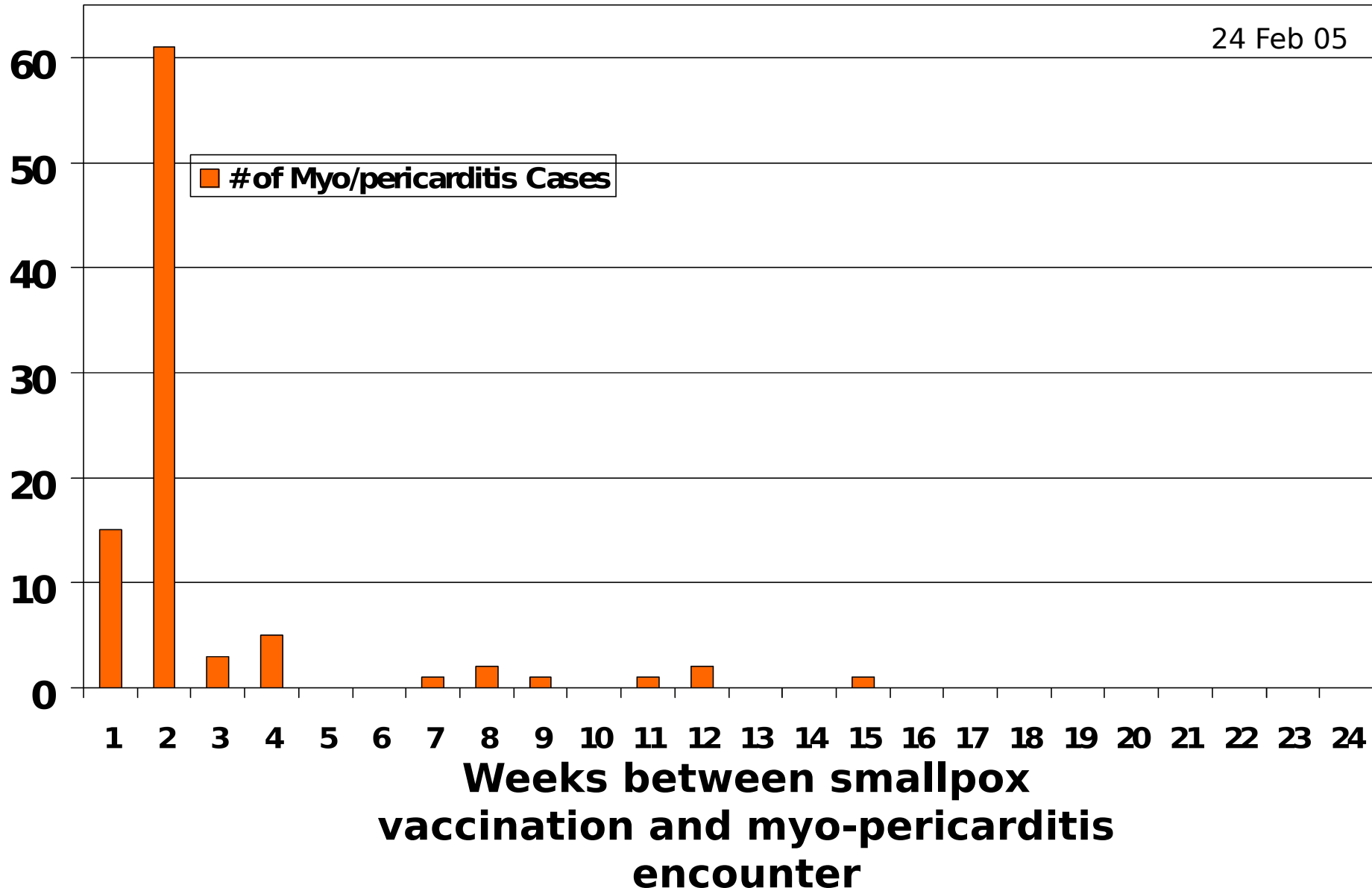
➤Program:

- **Support to outlying clinics, followup**



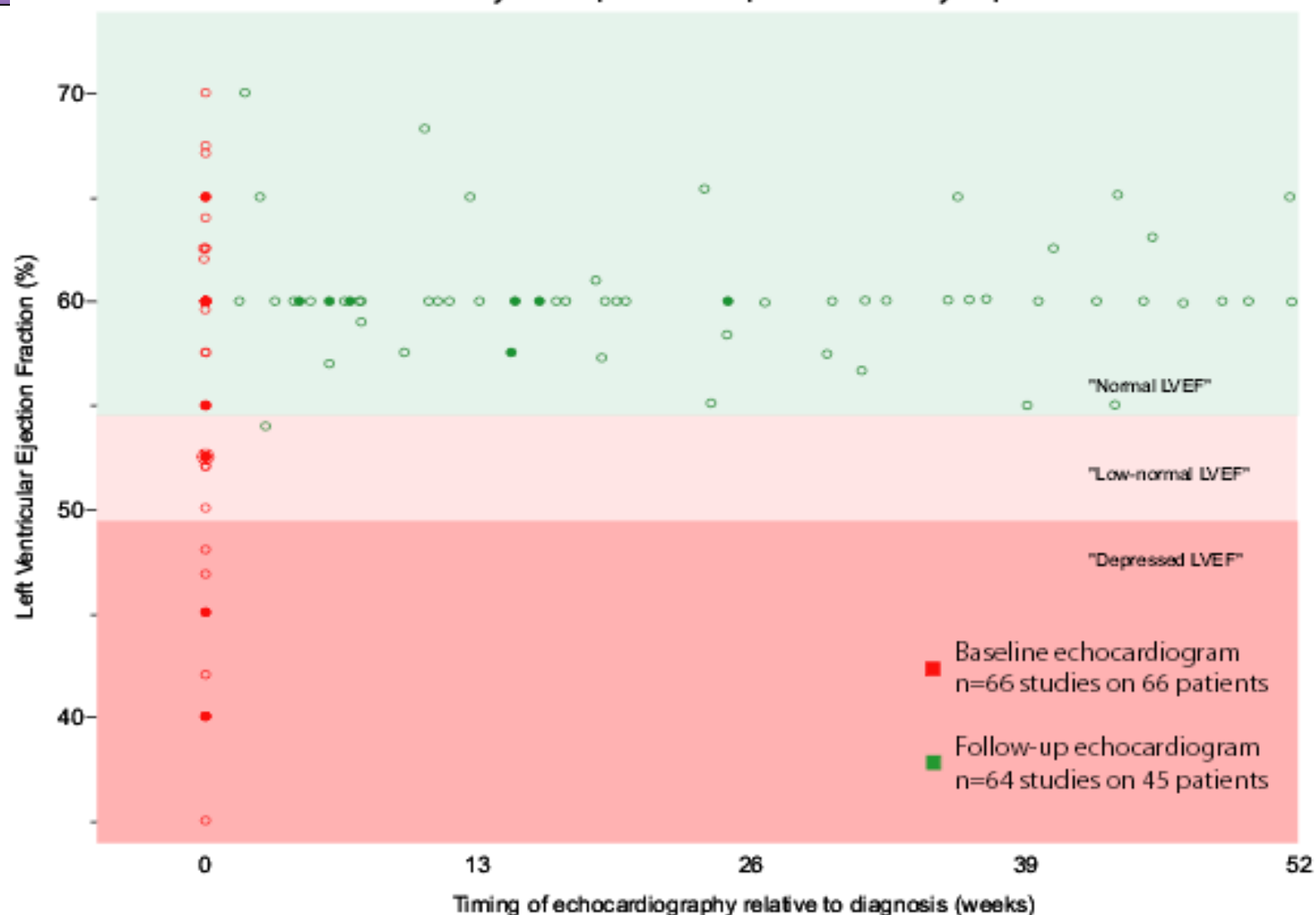
Myo-pericarditis after Smallpox Vaccine

24 Feb 05





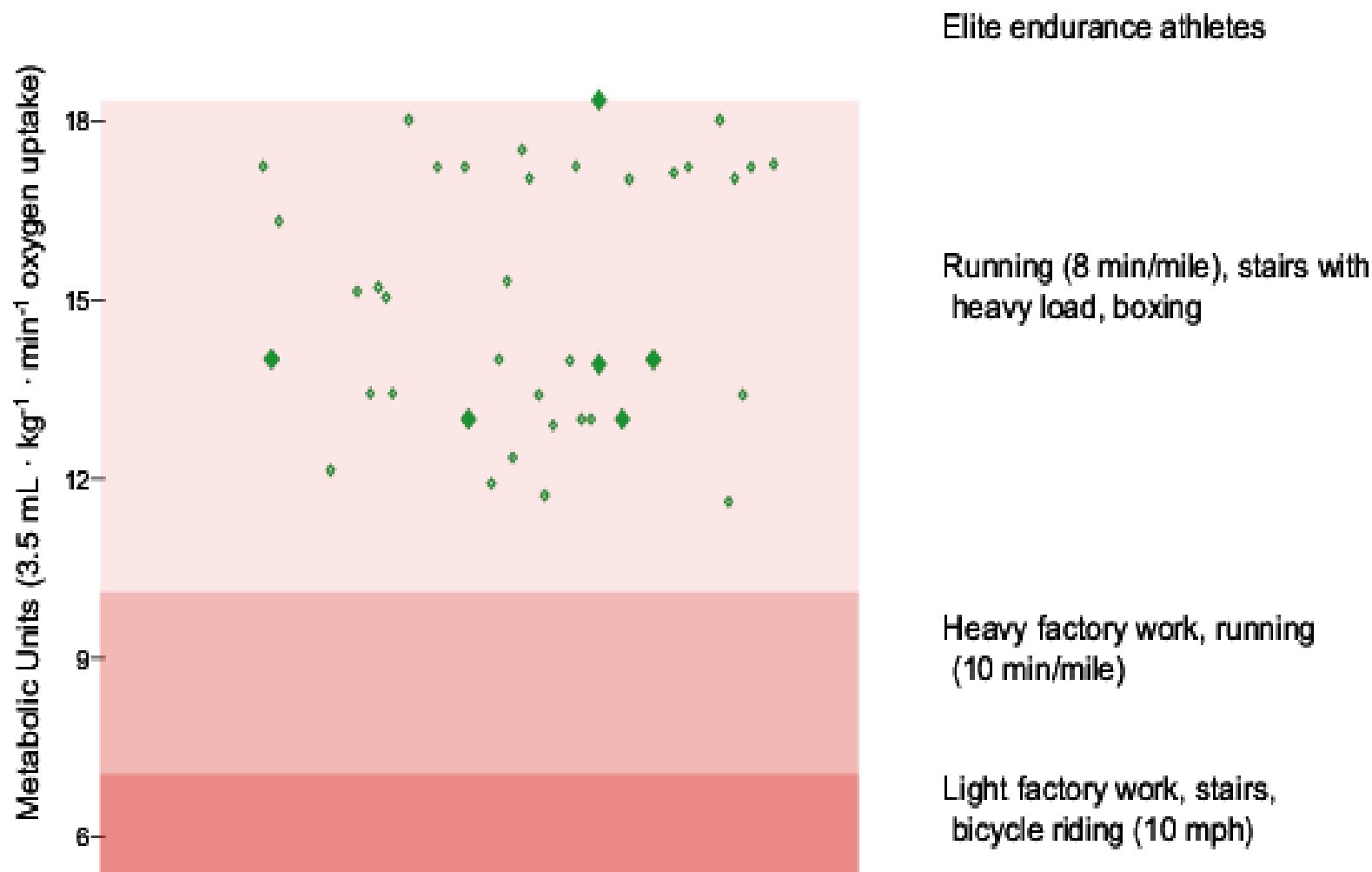
Recovery of ejection fraction relative to time of echocardiography stratified by complaint of persistent symptoms



Quantitative evaluation of ejection fraction relative to time of echocardiography since time of diagnosis. Time (0) indicates ejection fraction at time of initial presentation. Filled circles represent those patients reporting persistent symptoms, empty circles represent those with full clinical recovery. For all patients studied with reported continued symptoms, there was documented early normalization of ejection fraction.



Scatterplot of 36 patients undergoing functional assessment following smallpox associated myopericarditis



Eckart et al. J Am Coll Cardiol 2004; 44 (Jul): 201-205.

Results of treadmill testing using the Bruce protocol in 36 patients at a mean of 19 ± 14 weeks. Mean exercise duration 12.3 ± 1.8 min (9.0-17.0 minutes) to $95.7 \pm 5.8\%$ age-adjusted maximum predicted heart rate. Filled circles represent those with reported persistent symptoms, empty circles represent those reporting full clinical recovery.



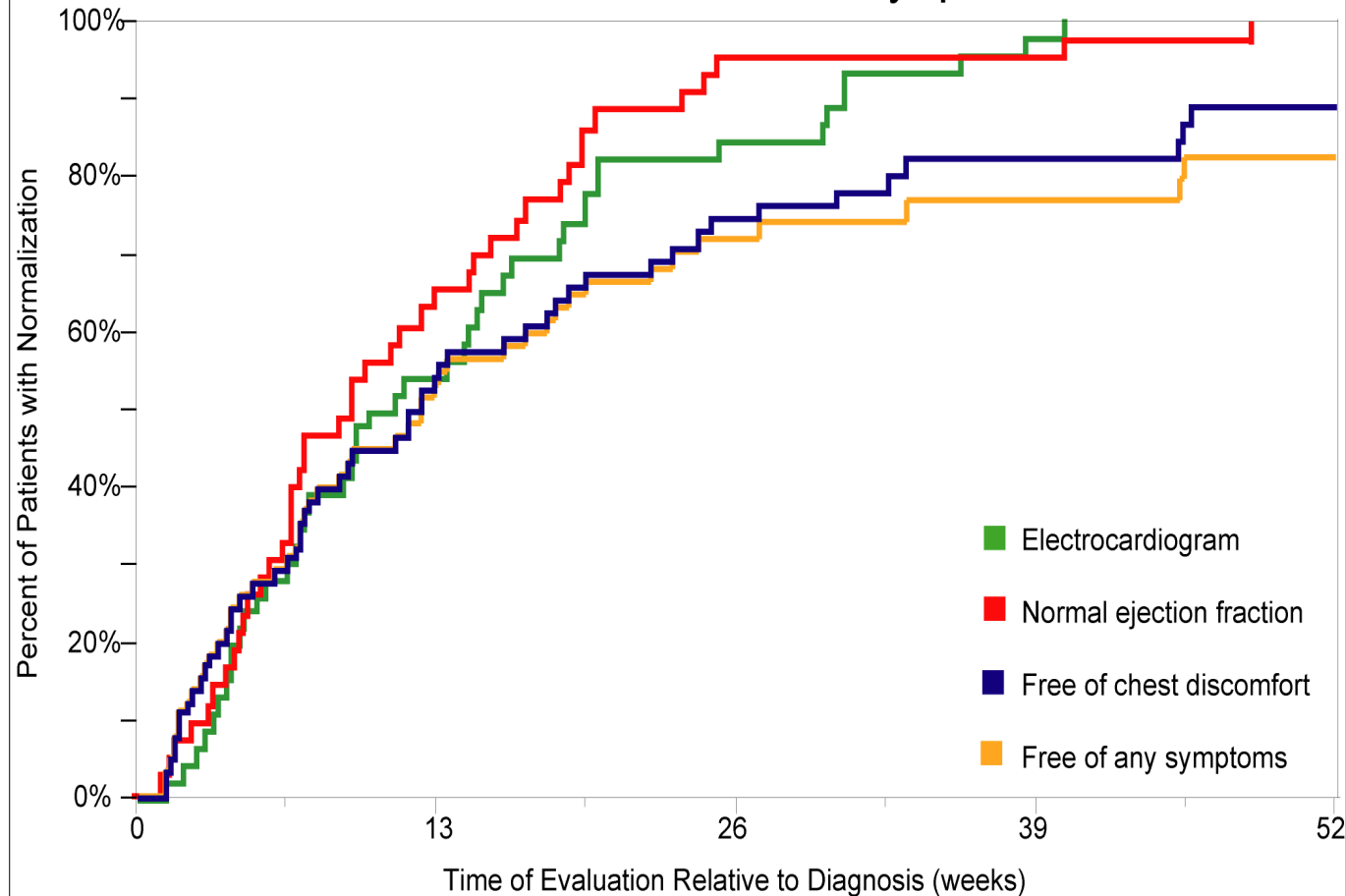
**Chest pain in
2nd week after
smallpox
vaccination?
Work up for
myo-
pericarditis.**

**Disproportion-
ately: male,
18-30 y/o,
primary
vaccinee**

**High recovery
rate**

→

Time to documented resolution or normalization of parameters felt to be indicative of recovery in patients after vaccinia-associated myopericarditis



Normalization of either electrocardiography, ejection fraction by echocardiography, or resolution of atypical continued chest discomfort relative to time of initial presentation. Time of evaluation denotes the time of performance of those studies (ECG or echocardiography) made available for review, or date of VHC provider interview documenting resolution of chest discomfort or any symptoms the patient reported as referable to smallpox vaccination (without attempt to note when patient reported resolution).



Myopericarditis Followup

Cardiac Magnetic Resonance (CMR) Imaging

- 33 patients received 43 CMR studies for initial evaluation (11 patients) or to evaluate persistent chest discomfort (22 patients).
- Mean time of imaging: 259 ± 293 days (median 241 days) after vaccination.
- 10 patients showed inflammation (30%) at median 320 d after vaccination.
- 1 of 3 with follow-up CMRs showed resolution at 678 days.
- 0 of 43 CMRs showed evidence of scar formation.

111-Indium-labeled White Blood Cell (WBC) Scan

- 12 patients received 19 scans, 9 patients had persistent chest discomfort.
- Mean time of imaging: 325 ± 239 days (median 347 days) after vaccination.
- Of 9 with persistent chest discomfort, 7 had inflammation (78%).
- Of 5 imaged when symptom-free, 0 had inflammation (0%).
- 0 of 12 had fixed perfusion defects in areas of healed inflammation.

Interpretation: Diagnostic, prognostic, therapeutic value unclear. Perhaps use to test people who present late, didn't have enzymes drawn, but now have persistent discomfort. Or to document *objective* abnormality. Need studies in controls (both carditis resolved and healthy).



Cardiac Conditions vis-à-vis Smallpox Vaccine

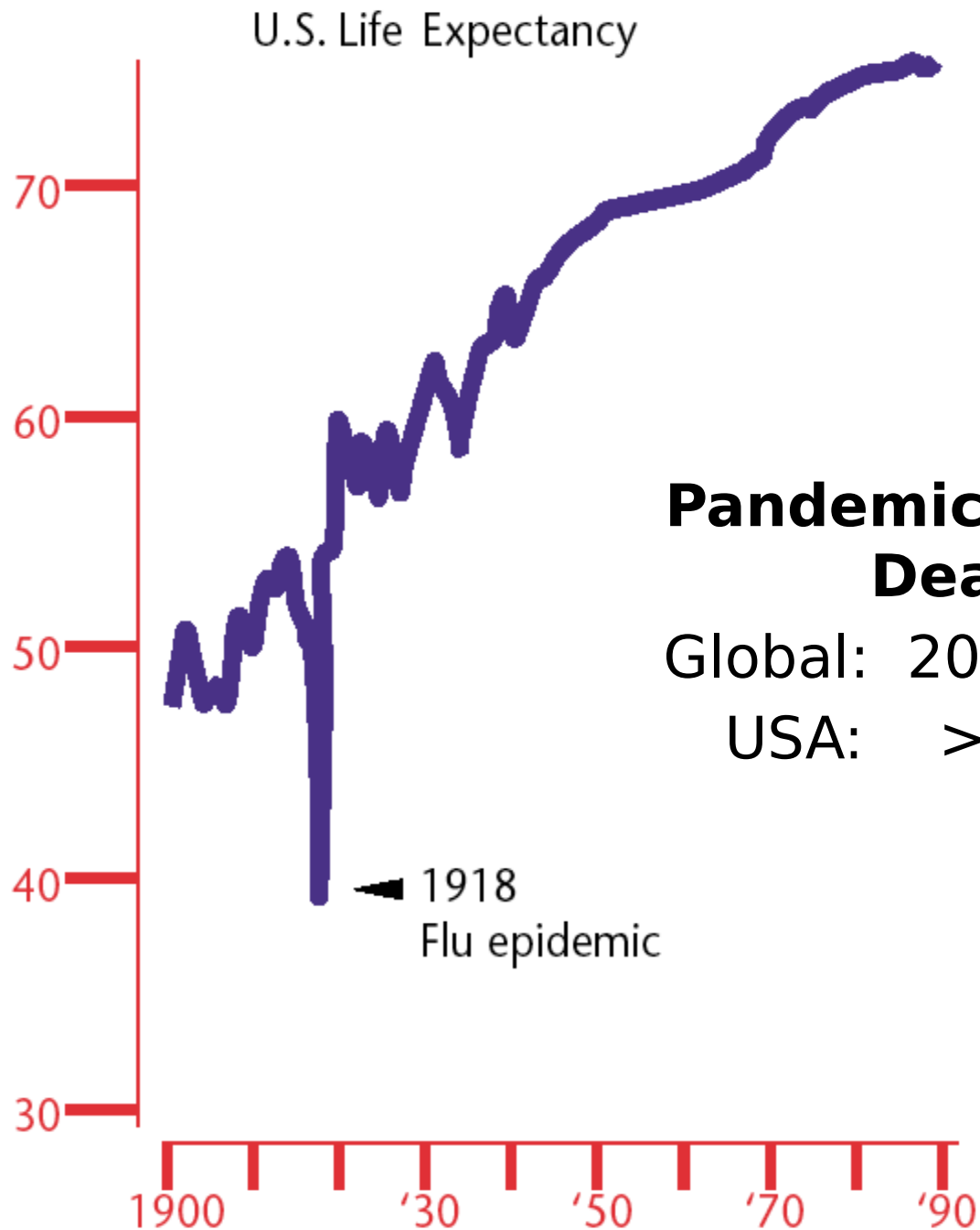
- **Smallpox Vaccination and...**
 - **Myo-pericarditis - Guilty, especially among male primary vaccinees**
 - **Dilated cardiomyopathy - Probably not guilty (“neutral”)**
 - **Ischemia - Innocent for military population**
 - **Neutral for civilian population**



- **ACIP – AFEB Smallpox Vaccine Safety Working Group**
 - Dec 02 – Jun 04 report nearing completion
 - Neurologic events report nearing completion
 - Sentinel case review nearing completion
- **Comment from SVSWG members...**



Emergency hospital during **influenza** epidemic, Camp Funston, Kansas, 1918



Pandemic Influenza Deaths

Global: 20-40 million

USA: > 500,000



Influenza Vaccine Shock: October 2004

Before the shortage: 3.77 million doses ordered

After Chiron's exit:

- 2.44 M dose *Fluvirin* shortfall (~65%)
- Purchases of *Fluzone* and *FluMist* increased
- Military: From universal to targeted (e.g., deployed, deploying)
- Beneficiaries: From broadly encouraged to targeted for medically high risk, matching ACIP
- Encourage *FluMist* to free up *Fluzone*
- DoD assisted States by not buying 200,000 doses of *Fluzone*
- Communications: Stress prevention and calm concerns
- Sufficient vaccine for minimum adjusted requirements



Succession of DoD Influenza Vaccine Policies

13 Oct 04: “Interim” guidance on managing shortage

- Critical operational forces (OIF, OEF, Korea) + trainees
- Medically high risk groups, per ACIP/CDC

25 Oct 04: “Final guidance” further defines high-priority groups

- Focus remains readiness and vulnerable populations

9 Nov 04:

- Maximize FluMist; follow package insert vs. ACIP

21 Dec 04: “Updated”

- Demand less than expected
- Add adults aged 50-64 y/o, contacts; expand FluMist

14 Jan 05:

- Use remaining vaccine for non-high risk and military



DoD Challenges in Using FluMist

- Shipment and Storage

- Dry-ice shipments outside lower 48 States, military aircraft
- Freezer volume, ~ 2-day shelf level
- Tradeoff: Convenient storage vs longer potency dating

- Customer Perceptions

- Live virus anxiety, perceptions of symptoms

- Simultaneous Vaccinations:

- No inactivated vaccines within 14 d, no live vaccines in 30
- Conflict with ACIP, until package insert revised 18 Mar 05

- Funding

- FY04 funds “unusable” after 30 Sep 04
- DSCP reassigned FY04 funds to alternate NSN



Next Fall We Get to Do It Again

Influenza (Pandemic) Surveillance

- Project Gargle – addressed separately
- Antiviral Stockpile – LTC Phillips

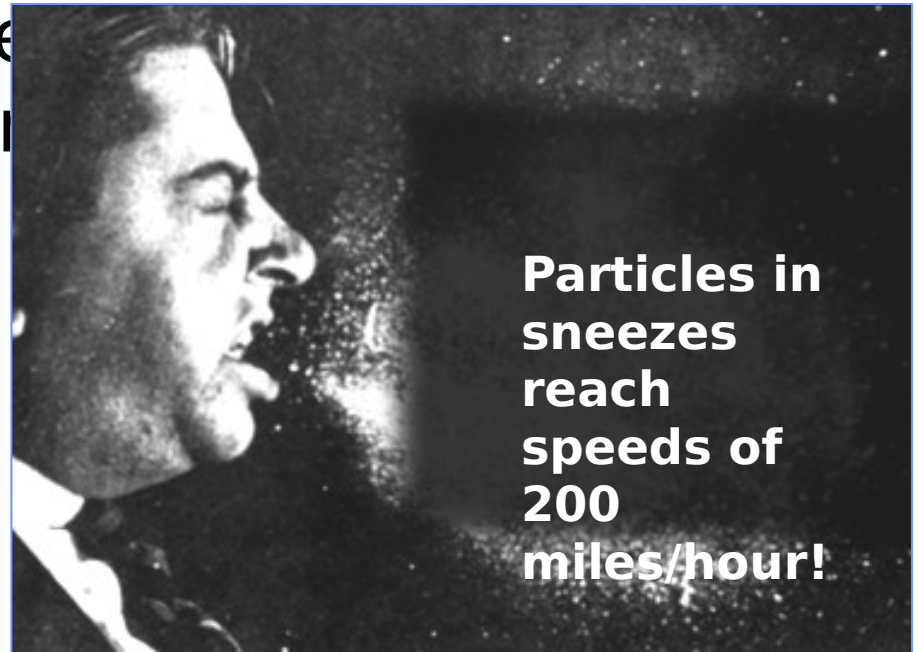
Looking ahead to 2005-06:

- Price per dose matters.
- If shortage repeats, repeat prioritization scheme of 2004, but looser.
- Install more refrigerator / freezer alarm systems.
- Explore enhanced vaccination of healthcare workers.



Transmission in Health Care Settings

- HCWs with asymptomatic and symptomatic influenza spread virus to patients and other staff
- Multiple studies show that 70% or more of HCWs continue to work despite being ill with influenza, increasing transmission to patients and co-workers



Transmission of Influenza: Implications for Control in Health Care Settings

Carolyn Buxton Bridges,¹ Matthew J. Kuehnert,¹ and Caroline B. Hall²

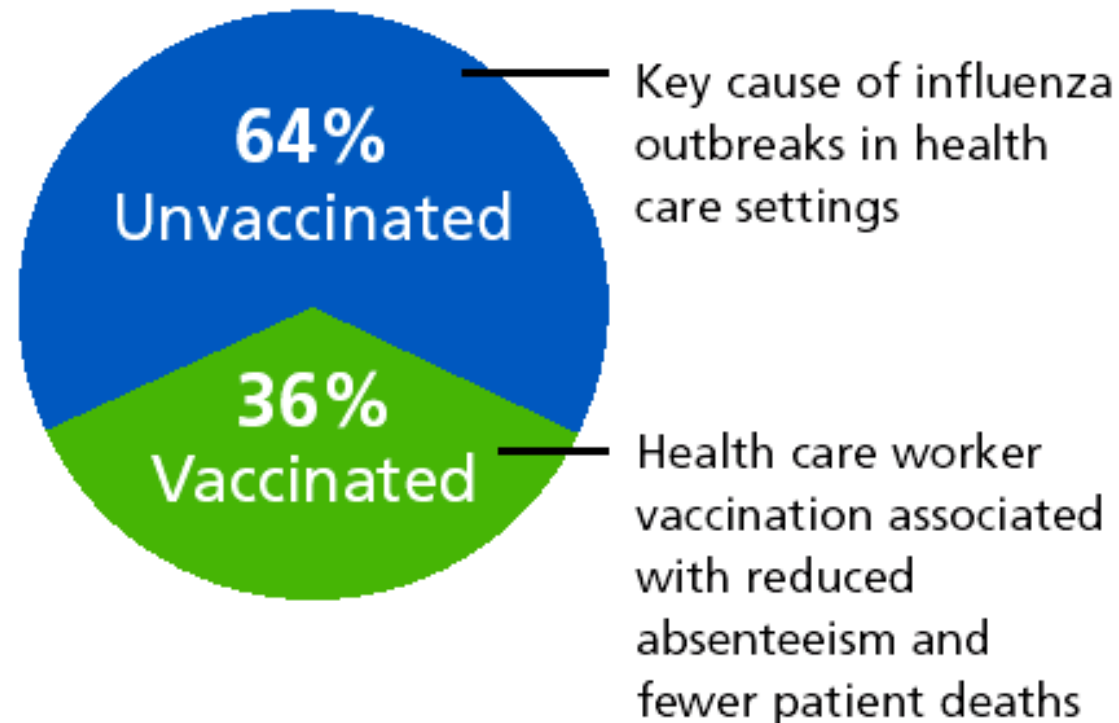
¹Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia; and ²Department of Pediatrics and Medicine, University of Rochester School of Medicine and Dentistry, Rochester, New York

Annual influenza epidemics in the United States result in an average of >36,000 deaths and 114,000 hospitalizations. Influenza can spread rapidly to patients and health care personnel in health care settings after influenza is introduced by visitors, staff, or patients. Influenza outbreaks in health care facilities can have potentially devastating consequences, particularly for immunocompromised persons. Although vaccination of health care personnel and patients is the primary means to prevent and control outbreaks of influenza in health care settings, antiviral influenza medications and isolation precautions are important adjuncts. Although droplet transmission is thought to be the primary mode of influenza transmission, limited evidence is available to support the relative clinical importance of contact, droplet, and droplet nuclei (airborne) transmission of influenza. In this article, the results of studies on the modes of influenza transmission and their relevant isolation precautions are reviewed.

Clinical Infectious Diseases 2003;37:1094



Average Annual Influenza Vaccination Rates in Health Care Workers



Source: CDC. Prevention and control of influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2003; 52 (RR8): 1-44.



- **Meningococcal A/C/Y/W-135 protein-conjugate vaccine**
- ***Menactra***, Sanofi Pasteur, licensed 17 Jan 05
- Presumably superior duration of protection
- ACIP recommends for 11 & 15 y/o, college
- JPMPPG: Services to substitute *Menactra* for *Menomune* asap, given that *Menomune* will be phased out eventually.
- Logistics: *Menactra* not yet available to DoD.
 - IM, rather than SC
 - Liquid, rather than freeze-dried powder
- AFEB comment



- **Acellular pertussis vaccine for adults and adolescents, as Tdap**
- ***Adacel***, Sanofi Pasteur, 4 P Ags, 11-54 y/o
- ***Boostrix***, GlaxoSmithKline, 3 P Ags, 10-18 y/o
- 0.5 ml, aluminum adjuvant, for age 11 and routine booster doses (interval after Td? 5-10 y?)
- Pertussis in adults (prolonged cough illness ~ 0.4% to 1.5% per year), adults as vectors to children (indirect)
- VRBPAC recommended licensure (summer 05?)
- Price differential ?
- ACIP recommendations ?
- DoD: Phased ? Abrupt ? (Gardner. *CID*, 1999)
- AFEB comment



- **Papillomavirus Vaccines**
- ***Gardasil***, Merck, types 6-11-16-18, aluminum, for both genders (eventually), 0-2-6 months
- ***Cervarix***, GlaxoSmithKline, types 16 and 18, AS04 (AI + MPL), for women, 0-1-6 months
- Morbidity / mortality in women vs. men, men as vectors to women (indirect value)
- Cervical dysplasias, cervical cancer (>400,000 cases, 230,000 deaths / year), genital warts
- Price ?
- ACIP recommendations ?
- DoD: Targeted by gender ? By age ?
- AFEB comment




- **Japanese Encephalitis Vaccine Supply**
 - Biken phasing out vaccine production line it markets via Sanofi Pasteur
 - Services funding purchase of JE vaccine stockpile via DSCP to supply vaccine sufficient thru FY10: 275,000 doses, \$17 million
 - Cell-culture-based vaccines expected to be FDA-licensed by then
 - AFEB comment



- **Vignettes:**
 - **Other**



MILVAX Web Site -

Address  <http://www.vaccines.mil/>

[http://
www.vaccines.mil/](http://www.vaccines.mil/)

Wednesday, September 22, 2004 12:56:34 PM ET

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MIL VAX

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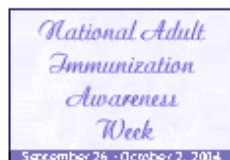
DoD Announces Anthrax & Smallpox Vaccination Program Expansion

William Winkenwerder, Jr., MD, assistant secretary of defense for health affairs, announced Tuesday, June 30th that the anthrax and smallpox vaccination programs would be expanded to include selected units within the U. S. Pacific Command and additional personnel now serving with the U.S. Central Command.

"The decision to protect additional personnel with these vaccines reflects our concern for their health and safety as well as the continuity of essential operations," said Winkenwerder. "When we began these vaccination programs we stated that we would periodically review them, evaluating the threats to our forces and vaccine availability. We recently completed such an evaluation and determined that the threat continues. In light of our successful implementation of these programs and the increased quantities of vaccine, we will include additional forces in the vaccination programs," he offered.

[more...](#)

National Adult Immunization Awareness Week
September 26 - October 2, 2004



NAIAW will begin in late September (September 26th through October 2nd) rather than the first half of October, as in previous years under the theme "Immunization:

Spokesperson's Training for Military Bio-Defense Vaccines

Register to become the local subject matter expert on the Anthrax Vaccine Immunization Program (AVIP) and the Smallpox Vaccination Program (SVP). Learn about program implementation and administration within your unit, electronic tracking systems, adverse events and risk communication as it applies to these programs.

Regional training locations for the next quarter include; PACOM, EUCOM & NCR.

[more...](#)

Pneumococcal Conjugate Vaccine Shortage Resolved

Since February 2004, CDC has recommended that 7-valent pneumococcal conjugate vaccine (PCV7), marketed as Prevnar® and manufactured by Wyeth Vaccines (Collegeville, Pennsylvania), be administered to healthy children on an abbreviated schedule to conserve the limited supply. Production capacity has been increased, and supply is now sufficient to meet the national demand for vaccine on the routine, 4-dose schedule. Effective immediately, CDC, in

The single best way to prevent the flu is to get vaccinated each fall



Epidemics of influenza typically occur during the winter months and have been responsible for an average of approximately 36,000 deaths/year in the United States during 1990-1999. Influenza viruses also can cause pandemics, during which rates of illness and death from influenza-related complications can increase dramatically worldwide. Influenza viruses cause disease among all age groups.

[more...](#)

Volunteers Needed at Ft. Campbell and Fort Carson to Support HHS Program





Quality Immunization Delivery

- **Quality:**
- Initial and continuing education of health-care providers and medics
- Education of vaccinees (ample time for)
- Screening for contraindications (listen well)
- Proper injection technique
- Storage & cold-chain management
- Excellent (electronic) record keeping
 - Gives credit. Avoids duplicate shots.
- Follow-up after vaccination



Project Immune Readiness

Welcome

John D. Grabenstein
Learner

Logout

❖ Welcome

❖ About Immune Readiness

❖ Goals and Objectives

❖ Target Audience

❖ Courses

❖ Other Resources Under Development

❖ Credit Information

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❖ Acknowledgements

❖ Disclaimer

❖ VHC (Vaccine Healthcare Center)

❖ Privacy

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AVAILABLE COURSES

Anthrax	Haemophilus Influenzae type b (HIB)	Hepatitis A
Hepatitis B - Advanced	Hepatitis B - General	Influenza
Introduction to Vaccination	Japanese Encephalitis	Measles
Meningococcal	Mumps	Pneumococcal
Polio	Rabies	Rubella
Smallpox Disease	Smallpox Administration	Smallpox Vaccine
Typhoid	Vaccine Storage and Handling	Varicella
Yellow Fever		

Take a Course

>50 seat hours of CE credit:
<http://www.vhcinfo.org>
<http://www.projectimmunereadiness.amedd.army>



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mil**

2nd edition, 2004



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and Childhood
Immunizations**



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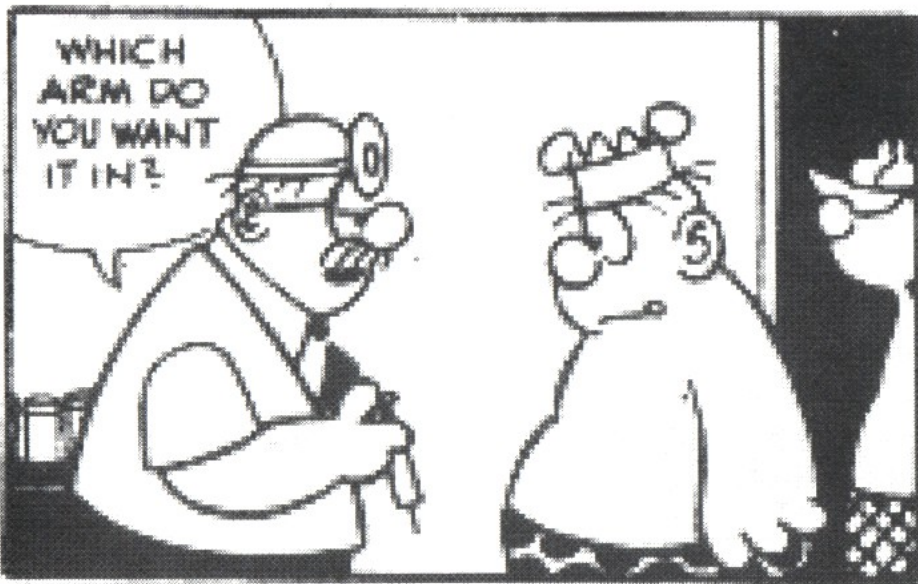
REVISED OCTOBER 2003

Vaccine Concerns: As Old As Vaccines Themselves



The Cow Pock - or - the Wonderful Effects of the New Inoculation
Vide - the Publications of ye Anti-Vaccine Society / J. Gillray, 1802





The Paradigm Has Shifted ...

- **Changing Military**
- **Changing Mission**
- **Emphasis on Reserve Components**
- **Economy / demographics**
- **Willing to ask questions**



- **Increasingly health conscious population**
- **Wealth of readily available information (good & bad)**



Care for Vaccinated People

- **Care:**
- Ongoing education of health-care providers & medics
- Clinical excellence
- Asking about vaccinations during follow-up care
- Reporting adverse events (VAERS)
- Keeping an open mind (science):
 - Myocarditis due to smallpox vaccine – yes
 - Heart attack due to smallpox vaccine – no
- Vaccine Healthcare Centers (VHC) Network
 - www.vhcinfo.org, askvhc@amedd.army.mil
- Clinical Guidelines for Managing Adverse Events after Vaccination
 - www.vaccines.mil/documents/564acg040909.pdf
- Exemptions as clinically warranted



Information Sources

- **Military Vaccine Agency, Army Surgeon General's Ofc**
 - Websites: **www.smallpox.mil,
www.anthrax.mil,
www.vaccines.mil**
 - Toll Free: **877.GET.VACC or DSN 761.4245**
- **DoD Vaccine Clinical Call Center:**
866.210.6469
- **Vaccine Healthcare Centers (VHC) Network:**
202.782.0411; DSN 662.0411 (www.vhcinfo.org)
- **Centers for Disease Control and Prevention (CDC):**
 - Website: **www.bt.cdc.gov**
 - CDC National Immunization Hotline:



- **Assure quality, continuous improvement**
- **Immunization University**
 - **Enhanced education and training**
 - **Vaccinator competency per JCAHO**
 - **Clinic self-assessment program (coached)**
- *Science – Quality – Care – Confidence*



PROPOSAL: *Immunization University*

DRAFT	school of imztn science & care	academy of clinic opns & quality	registrar
Standards	Imztn standards, AE guidelines	Self-assessment program, SOPs	Clinic directory
Education & Training	Proj Imm Readiness, Toolkit, Y8, Imztn Leaders Course	Training file, competencies, Shots R Us, ITS	Vaccinator directory, transcripts
Consultation	Vax Clinical Call Ctr, VHCs, case mgmt, sick call	vaccines.mil, GET-VACC	
Communicatio n		Vaxnator-patient relationship	Listserv
Inquiry	Clinical investigation, registry, surveillance	Coverage, currency, readiness	



Seek Excellence

Excellence in immunization requires:

- Reliable science, published, with eyes & ears remaining wide open.
- Quality in shots given, exemptions granted, vaccines used, documents maintained.
- Care, in vaccinating and in follow-up, regardless whether vaccine caused problem or not.
- Thus earning the confidence of the troops and their families, with mutual understanding.

Give your best





- **Adenovirus Vaccines 4 and 7**
 - **Manufacturing Status**
 - **Shelf-life stability testing. Refrigerator out-of-specification.**
 - **Clinical Trial Status**
 - **Phase 1 studies: seroconversion, shedding virus. Analysis in progress. Well tolerated.**
 - **FDA meeting upcoming.**
 - **Next trial: Searching for sites (1 to 3).**
 - **Retrospective Policy Search**